IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
ETHICON WAVE 8 CASES LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO PRECLUDE OR LIMIT OPINIONS OF EXPERT RICHARD ELLERKMANN, M.D.

Defendants submit this opposition in response to Plaintiffs' Motion to Preclude or Limit Opinions of Defense Expert Richard Ellerkmann, M.D. [Dkt. 6894]

I. Dr. Ellerkmann's Is Not Offered as An Expert Regarding the Pre-Marketing Design Protocols or the Design Process Utilized by Ethicon.

Plaintiffs argue that Dr. Ellerkmann's opinions regarding the design of Gynemesh and Prolift should be excluded because he has never designed a mesh product, does not hold specialized degrees in chemical engineering or polymer chemistry, has not done any bench research on polypropylene, and is not familiar with Ethicon's internal design process and protocols. Pfs. Mem. at 4, 8. In making this argument, Plaintiffs conflate two distinct subjects: the safety and efficacy of Gynemesh/Prolift as sold by Ethicon, versus compliance with medical device design protocols and regulations. Dr. Ellerkmann is proffered to opine on the first subject, but not the second. *Compare, In re Boston Sci. Corp. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2326, 2018 WL 2440257, at *2 (S.D.W. Va. May 30, 2018) ("Without any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that

these procedures were departures from the norm, not followed by BSC, or lacking in any way."), *with, In re: Ethicon, Inc.*, No. 2:12-MD-02327, 2016 WL 4536885, at *3 (S.D.W. Va. Aug. 30, 2016)(although Dr. Margolis was not a biomaterials expert, does not possess an engineering degree in materials science, and has not performed "bench research" on polypropylene opinions, the Court found that "[s]uch qualifications are not necessary to opine on the clinical properties of mesh . . .").

Dr. Ellerkmann has not and will not offer opinions regarding Ethicon's design protocols or departures from other design procedure norms. *See also* MDL 2327 DKT. 2679 Memorandum Opinion and Order Re: Denise Elser, M.D. (distinguished between opinions regarding the process of designing a product and opinions regarding the safety of a product as designed and sold).

As is clear from Dr. Ellerkmann's report and deposition testimony, he offers opinions regarding the safety and efficacy of Prolift and Gynemesh PS, including the opinion that these mesh products offer superior anatomic support to prolapsed organs and do not lead to a significant increased risk of post-operative complications. Ex. A, General Expert Rpt. of Richard Marcus Ellerkmann, M.D., at 7 & 12-13. Dr. Ellerkmann is well-qualified to offer these opinions.

Dr. Ellerkmann is board certified in obstetrics and gynecology, as well as female pelvic medicine and reconstructive surgery. He is a Fellow of the American Board of Obstetrics and Gynecology. Ex. A, Ellerkmann Rpt. at 1; Ex. B, Ellerkmann CV. He currently serves as the Director of the Urogynecology Center at Mercy in Baltimore and is an Assistant Professor in Obstetrics and Gynecology, Section of Urogynecology and Reconstructive Pelvic Surgery, at John Hopkins School of Medicine. *Id.* He has performed the full range of gynecologic and

urogynecologic surgeries over the past 20 years. *Id.* He has utilized Gynemesh PS products, including TVT-O, TVT Secur and TVT Exact devices and estimates that he has performed over 1,000 surgeries with the TVT devices during his career. Ellerkmann Rpt at 2. Dr. Ellerkman has also utilized Gynemesh PS, Prolift, and Prolift +M for the treatment of pelvic organ prolapse in hundreds of patients including placement during sacrocolpopexy and transvaginally. *Id.*

Dr. Ellerkmann has analyzed polypropylene medical devices used to treat female pelvic medicine and reconstructive surgery in connection with his formal training, and identified himself as an expert on Prolift prior to engaging in this litigation. Ex. C, Ellerkman Dep. at 144:5-145:4. His publications include studies assessing the Gynemesh TVT device and the largest randomized controlled trial comparing a standard retropubic midurethral sling to a mini-sling (TVT versus TVT Secur). Ellerkmann Report at 2.[1] Indeed, Dr. Ellerkman became an Ethicon preceptor for TVT in 2000, and has trained other surgeons on patient selection and correct surgical techniques for TVT, TVT-O, and Gynemesh PS/ Prolift including didactic lectures, telesurgery, and cadaver labs since 2000. *Id.* at 2-3.

Dr. Ellerkmann is well-versed in the known complications associated with pelvic floor surgery, with and without mesh products. In his roles as Chief and Director of various residency and urogynecology fellowship programs, he became am familiar with national standards and experienced in the curriculum as set forth in the U.S. for pelvic surgeons. *Id.* He has conducted an independent scientific literature review, and his opinions are supported by hundreds of published articles and studies. Ellerkmann Dep. at 40:13-19; Ex. D, Ellerkmann Reliance List.

[1] *Citing* Barber MD, Ellerkmann M, et al.; Foundation for Female Health Awareness Research Network.. Single-incision mini-sling compared with tension-free vaginal tape for the treatment of stress urinary incontinence: a randomized controlled trial. Obstet Gynecol. 2012 Feb;119(2 Pt 1):328-37. PubMed PMID: 22270285; Sanses TV, Ellerkmann RM, et al. Outcomes of Retropubic Synthetic Midurethral Gynecare TVT Slings When Performed by Urogynecologists, Urologists, and General Gynecologists in a Private Community Hospital. Female Pelvic Med Reconstr Surg. 2010 Jul;16(4):238-41. PubMed PMID: 22453349.

He has designed medical devices for the treatment of female urinary incontinence in the past, and was involved in pre-market design workshops and the market validation of TVT Secure. Ellerkmann Dep. at 78:9-24.

In *Mathison v. Boston Scientific Corporation*, this Court found that a board-certified urologist, Dr. Lonny S. Green, who had conducted nearly 3,000 sling procedures and practiced for twenty years was qualified to opine that the mesh product does not shrink, contract, degrade, or cause systemic infections. No. 2:13-CV-05851, 2015 WL 2124991, at *27-28 (S.D. W. Va. May 6, 2015). The Court further found that the doctor's clinical experience and review of scientific literature were sufficiently reliable bases in forming the opinion. *Id.*[2]

Like Dr. Green, Dr. Ellerkman has sufficient familiarity and experience with mesh slings generally, pelvic floor prolapse procedures, and the Gynemesh, TVT and Prolift devices in particular to provide reliable opinions on whether they are safe and effective, and whether they shrink, contract, or degrade.

II. Dr. Ellerkman's Reliance on His Surgical Experiences is Appropriate

[2] *See also, In re: Ethicon, Inc.,* No. 2:12-MD-02327, 2016 WL 4536885, at *3 (S.D.W. Va. Aug. 30, 2016)(although Dr. Margolis was not a biomaterials expert, does not possess an engineering degree in materials science, and has not performed "bench research" on polypropylene opinions, the Court found that "[s]uch qualifications are not necessary to opine on the clinical properties of mesh . . ."); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013) (Goodwin, J.) (ruling that an expert was qualified to opine on product design and biomaterials because he had "extensive experience with pelvic floor disorders and the use of mesh to treat such disorders"); *See, e.g., In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2017 988838, at * (S.D.W. Va. Aug. 30, 2016) (denying plaintiffs' motion to exclude testimony by board-certified obstetrician-gynecologist regarding the "safety and efficacy" of SUI and POP products); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (permitting board-certified urologist with no stated "design" expertise to testify to the safety and effectiveness of mesh as he had "performed almost 3,000 sling procedures," and "cites numerous studies and academic papers throughout his expert report to support his opinion that the Obtryx is both safe and effective"); *Wilkerson v. Boston Sci. Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *24 (S.D.W. Va. May 5, 2015) (rejecting attempt to exclude testimony by an obstetrician-gynecologist on the "safety and effectiveness" of midurethral slings and holding that the clinician's extensive experience implanting the devices "along with his review of the existing literature, provides a reliable basis for his opinions on the safety and efficacy of the Advantage Fit.") .

Plaintiff incorrectly argues that Dr. Ellerkmann should be excluded from giving "design opinions" because "he relies" on his own low complication rates from his practice but has not provided the data from his database to confirm these rates. Plfs Mem. at 7. However, Dr. Ellerkmann only offered his personal complication rates when questioned by Plaintiffs' counsel at his deposition. Ex. C, Ellerkmann Dep. 15:5-22. In fact, Plaintiffs' counsel acknowledged as much in her questioning: "Q: And I don't see anywhere in your expert report where you say that you intend to state an opinion as to what your complication rate is with the Prolift." *Id.* Dr. Ellerkmann did not rely on or reference this personal complication rates in his expert report, but rather extensively cited published studies, including his own published works, when identifying known rates of complications associated with Gynemesh PS products, including Prolift. *See* Ex. A, Ellerkmann Rpt. at 3 (citing his own published studies with documented complication and reoperation rates below 5% with various gynemesh sling products); *Id.* at 10-12 (citing numerous published studies collecting complication rates); *Id.* at 16-21 (same).

Plaintiffs' citation to cases in which experts proposed to opine regarding personal complication rates without providing data to support those rates are inapposite. Dr. Ellerkmann only offered his personal complication rates when Plaintiffs' counsel questioned him, and even then he explained those rates were drawn from verifiable data, and that they were the same rates he provided to his patients. Ex. C, Ellerkmann Dep. at 158:5-159:23. As noted above, these rates are consistent with complication rates found in published studies cited by Dr. Ellerkman. This Court has recognized that a physician may testify that complication rates found in literature are verified by his personal experience. *See, e.g., Tyree v. Boston Scientific Corp*, 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014) (expert's opinion about safety and efficacy was reliable where opinion was based upon "minimal complications in his clinical practice" which was "'on par

with the findings of [the] studies' he cites throughout his expert report"); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *12, *36 (S.D. W. Va. Apr. 28, 2015) (finding Dr. Galloway's method of considering scientific articles and drawing on his clinical experience to reach his opinion regarding degradation to be methodologically sound and allowing Dr. Culligan "by way of his experience with the Uphold device and his review of the relevant scientific literature" to opine how these procedures compare).

Dr. Ellerkmann's opinions regarding the safety and efficacy of the design of Gynemesh PS and Prolift are supported by ample independent research, cited throughout the body of his report *and* in his Reliance List. His opinions are consistent with his personal clinical experience and knowledge, also detailed in his report. Dr. Ellerkmann's opinions are not, as suggested by Plaintiffs, solely based upon unverifiable personal complication rates. Moreover, as this Court has recognized, *Daubert* does not require independent verification of "every single clinical experience [the physician] had over the course of his career," because otherwise, "the court would never make it past pre-trial motions." *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Doc. 265, p. 40 (S.D.W. Va. Nov. 20, 2014); *see also Winebarger*, 2015 WL 1887222, at *34 (finding that expert's lack of "exact statistics" about the outcome of his patients did not render his opinions based on personal experience unreliable and that "such detail is not required under Daubert to opine as to 'large-scale safety and efficacy of the Uphold device'"); *Trevino*, 2016 WL 2939521, at *33 (same). *See, e.g., Tyree v. Boston Scientific Corp*, 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014) (expert's opinion about safety and efficacy was reliable where opinion was based upon "minimal complications in his clinical practice" which was "'on par with the findings of [the] studies' he cites throughout his expert report").

Plaintiffs' motion to exclude Dr. Ellerkmanns' "design" opinions should be denied.

III. Dr. Ellerkman is Qualified to Opine Regarding the Gynemesh and Prolift Warnings.

Defendants acknowledge that this Court has previously held that an expert may not state his opinion using legal terms of art, *Ramsey v. Boston Sci. Corp.*, No. 2:13-cv-15223, 2016 WL 2939526, at *2 (S.D. W.Va. May 19, 2016), nor may he opine that a particular warning label "adequately inform[s] users of the dangers associated with using the device." *Hall v. Boston Scientific Corp.*, No. 2:12-CV-08186, 2015 WL 868907, at *10 (S.D.W. Va. Feb. 27, 2015). Accordingly, Dr. Bowling will not offer the opinion that the IFUs in issue "adequately" warned of potential complications. Rather, Dr. Elerkmann will opine regarding which risks exist (or do not exist) associated with the products in issue, whether these risks were identified in the IFUs or were otherwise generally known to pelvic floor surgeons. "[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015) (quoting *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09–md–02100, 2011 WL 6301625, at *11 (S.D.Ill.Dec.16, 2011)).

Dr. Ellerkmann has not been designated, nor does he hold himself out as, an FDA regulatory expert or expert regarding industry standards governing warnings. See Plfs' Mem. at 10. For these reasons, the cases cited by Plaintiffs are off-point. For example, in *In re C.R. Bard, Inc.*, 948 F.Supp.2d 589, 611 (S.D.W. Va. 2013) *amended on reconsideration in part* (June 14, 2103, the expert sought to opine regarding what Bard "should have done with respect to its warnings" based on what "Bard knew" and what was disclosed in its "510(K) applications." Because the expert had no federal regulatory expertise or familiarity with industry labeling practices, the

Court found the expert unqualified to opine regarding whether the warnings and the defendants' process of preparing warning labels were adequate. *Id.*

In contrast, Dr. Ellerkmann does not seek to offer opinions regarding what Ethicon "should have done" with regard to developing its warning labels or whether Ethicon complied with federal regulations (or industry standards) when developing warning labels. Indeed, he expressly disavowed any attempt to offer these types of opinions when repeatedly pressed by Plaintiffs' counsel at his deposition. Ex. C, Ellerkmann Dep. at 95:22-97:98:23 ("Q: Is it an appropriate warning now as we sit here in 2018. [objection omitted] A: They chose to list that as a potential complication. I'm not here to tell you whether that's right or wrong, but I am telling you that I don't believe that contraction of tissue is a result of mesh implantation.")

As a pelvic floor surgeon with 20 years of experience, who has published studies on Gynemesh PS products, and conducted independent research in support of his opinions, Dr. Ellerkmann is qualified to testify regarding the potential risks caused by the product in issue and whether those risks are identified in the labels. *See* Ex. C, Ellerkmann Dep. 154:17-155:4 (explaining that "in addition to the literature reviewed for today's deposition and for the report, the foundation for my opinion and expert report is based on my experience, my clinical experience, my communications with other colleagues, and my review of literature over the years as well as specific review of the literature for preparations for the report."). Moreover, he has directly participated as a member of the board of advisors in the development of a medical device for use in the treatment of female stress urinary incontinence, including providing counsel regarding the warning for use. Ellerkmann Dep. 66:17-67:1.

Additionally, as a residency director at John Hopkins, and through teaching residents and participating in fellowship training, Dr. Ellerkman has expertise and knowledge regarding the

expected knowledge of pelvic floor surgeons. *Id*. at 139:16-140:23. *See Waterhouse v. R.J. Reynolds Tobacco Co.*, 368 F. Supp. 2d 432, 437 (D. Md. 2005), *aff'd*, 162 F. App'x 231 (4th Cir. 2006) ("expert testimony is required with respect to the state of common knowledge of smoking hazards during the smoking career of a plaintiff and that that testimony must be rendered by competent experts."); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (testimony regarding common knowledge is critical in failure to warn cases, and expert opinion concerning knowledge of average consumer was appropriate and relevant).

Dr. Ellerkmann is qualified to offer the opinions he identifies in his expert repot. Because Ethicon agrees that Dr. Ellerkmann will not offer opinions drawing ultimate legal conclusions, Plaintiffs' motion should be denied as moot.

IV. Dr. Ellerkmann's Opinions Are Supported By Reliable Methodology and Relevant Scientific Literature.

Plaintiffs' argue that Dr. Ellerrkmann's opinions should be excluded because the "basis for his conclusions has not been properly disclosed to Plaintiffs." Plfs. Mem. at 11. Plaintiffs' position is untenable. Dr. Ellerkmann's expert report is heavy with citations for every opinion he offers, on nearly every page of his report. *See*, Ellerkmann Rpt. It is abundantly clear which publications, studies, and experiences he is relying on for each of his substantive statements. In addition to these internal citations, his 23-page Reliance List contains citations to over 200 scientific publications. Ex. D, Reliance List.

In support of their position, Plaintiffs point to the fact that Dr. Ellerkmann could not recall reviewing certain materials on his Reliance List. Although Plaintiffs' imply that Dr. Ellerkmann's Reliance List is inaccurate, and "it is unknown what materials Dr. Ellerkmann reviewed or did not review from his reliance list," Plfs. Mem. at 12, that is not the case. Dr. Ellerkmann clarified this issue in his deposition. As he explained, he "was not sure" if he

reviewed certain Ethicon employee depositions and email communications in forming his opinions, although they were provided to him and listed on the Reliance List. Ellerkmann Dep. at 41:3-43:5 ("So Counsel, some of the depositions and some of the email communications I would have probably not reviewed. I was looking more at Level 1, Level 2 literature as I did my report."). Specifically, he referred to two employee depositions that he did not recall reading: Pete Hinoul and Marty Wiseberg. Ellerkmann Dep. at 40:20-43:5. He also testified that review of Ethicon employees' depositions regarding the products in issue would not be necessary to his scientific analysis regarding the safety and efficacy of Gynemesh PS and Prolift. As Dr. Elkermann explained, his opinions are "based on review of the literature specifically with attention to Level 1 and Level 2, not to expert testimony and less quality evidence." Ellerkmann Dep. 108:21-109:9. Depositions of employees "wouldn't have any bearing on" his analysis of the scientific literature regarding these products. *Id.* at 109:16-110:19.

And, nearly every substantive statement contained in his expert report includes specific citation to the precise published studies that support the statement. *See* Ellerkmann Rpt. *See also Tyree*, 54 F. Supp. 3d at 559-60 ("Dr. Blaivas's failure to recall which articles supported his opinion as to safety is an insufficient reason to find his methodology unreliable" because he "has extensive experience . . . and considered scientific literature in forming his opinions as evidenced by his relied upon list.") (internal citations omitted).

Because Dr. Ellerkmann employed a reliable methodology based on his extensive experience and independent review of scientific literature cited throughout his expert report, Plaintiffs' motion should be denied.

CONCLUSION

For the reasons stated above, the Court should deny Plaintiffs' motion to exclude the opinions and testimony of Dr. Richard Marcus Ellerkmann.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage
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